

Application No. 09/554,835

MARKED-UP COPY OF AMENDED CLAIMS:

Please amend claim 2 as follows:

2. (AMENDED) A method for treating or preventing diarrhea mediated by pathogenic fungi in a mammal ~~mediated by pathogenic fungi~~ comprising administering to the mammal *Escherichia coli* coli strain DSM 6601.

REMARKS

Applicant has amended the only pending claim, claim 2, in response to the rejection set forth under Section 112, second paragraph. Specifically, claim 2 has been amended to more clearly specify that the method claimed is directed to treating and preventing diarrhea mediated by pathogenic fungi. Independent claims 3 and 4 have been added. Claim 3 is directed to a method for treating diarrhea mediated by pathogenic fungi, and claim 4 is directed to a method for preventing diarrhea mediated by pathogenic fungi. Support for the new claims is found in the original specification. Accordingly, no new matter has been added. Therefore, Applicant respectfully requests entry of the amendments.

Claim 2 has been rejected under 35 U.S.C. § 102(b) as being anticipated by *Hockertz* or *Lodinova-Zadnikova et al.*, or under 35 U.S.C. § 102(a) as anticipated by DE 196 37 936. The Examiner's position is that *Hockertz* discloses a one step administration of DSM 6601 to mice infected with *Candida albicans*. The Examiner also contends that *Lodinova-Zadnikova et al.* discloses a one step administration of DSM 6601 to humans, and that this administration would inherently prevent fungi mediated diarrhea. Finally, the Examiner contends that DE 196 37 936 teaches the administration of DSM 6601 and nystatin to treat intestinal *Candida* infection. Applicant respectfully traverses the rejections.

The *Hockertz* reference is directed to the use of DSM 6601 for its ability to enhance the immune response against bacterial or fungal infections in mice. DSM 6601 was administered orally to the mice, which were then subsequently exposed to an intravenously administered infection with pathogenic bacteria or fungi. The results simply demonstrated a parasite reduction in the kidneys after prophylactic oral

treatment. There is no teaching or suggestion that the disclosed method would be effective for treating or preventing diarrhea mediated by pathogenic fungi. Thus, Applicant respectfully submits that the presently claimed invention is not anticipated by *Hockertz*.

With respect to the *Lodinova-Zadnikova et al.* reference, this article merely discloses the administration of DSM 6601 to newborns and its potential use as a prophylactic for bacterial infections. The issue is the problem of a prophylactic treatment against an undesired colonization in the gastrointestinal tract of newborn babies through germs in their surroundings. None of the children treated suffered from, or were treated for, diarrhea, but the symptoms of a miscolonization in newborn babies manifest themselves in impediments in growth, lacking immunological response, etc. The reference does not even suggest the use of the claimed *E. coli* strain in the case of diarrhea in human beings caused by yeasts, and by no means the use among other mammals. Plainly, this reference neither teaches nor suggests that DSM 6601 has anti-fungal activity. Moreover, with respect to the Examiner's contention of inherency, it has been observed by the courts that inherency requires that something necessarily and always occurs. The fact that a result may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Accordingly, Applicant submits that this reference cannot anticipate the claimed methods.

Finally, DE 196 37 936 merely discloses the use of the claimed *E. coli* strain in combination with the antimycotic nystatin. In this case, the *E. coli* strain is used as a bioadhesive for prolonging the retention time of the nystatin at the site of absorption and/or action. Plainly, if the investigators realized or intended the *E. Coli* strain to be the

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sole agent for treatment, there would be no need for the addition of the additional anti-fungal agent nystatin. Accordingly, Applicant respectfully submits that the presently claimed invention is not anticipated by DE 196 37 936.

In view of the foregoing, Applicant respectfully submits that the presently claimed invention is not anticipated by any of the cited references. Accordingly, reconsideration and withdrawal of the grounds of rejections are respectfully requested.


As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

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